IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
BEAUFORT DIVISION

The United States of America, et al. Plaintiffs, vs. Bluewave Healthcare Consultants, Inc., et al. Defendants.	)	**CA No.: 9:14-cv-00230-RMG** (Consolidated with 9:11-cv-1593-RMG and 9:15-cv-2485-RMG)

THE UNITED STATES' REPORT
PURSUANT TO LOCAL RULE 26.03 (D.S.C)

All Parties to this action are filing contemporaneously herewith a Joint Report pursuant to Federal Rule of Civil Procedure 26(f) and a Joint Submission Regarding Discovery Schedule and Limits (hereinafter "Joint Submission,") addressing and summarizing the Parties' requested discovery schedule and limits on certain discovery, as required by Local Rule 26.03 (D.S.C.), together with certain attachments. Also on this date, the United States is providing to the other Parties its Initial Disclosures pursuant to Federal Rule of Civil Procedure 26(a)(1).

In their Joint Submission, the Parties anticipated filing separate statements concerning areas of disagreement regarding the discovery schedule and limits and providing the additional information required under Local Civil Rule 26.03 and Federal Rule of Civil Procedure 26(f). The United States provides that additional information herein.

1. **Local Civil Rule 26.03(A)(1)**: A short statement of the facts of the case.

The United States filed a Complaint in Intervention to recover losses from false claims submitted to the Medicare and TRICARE programs as a result of the sustained fraudulent course of conduct of Defendants Berkeley Heartlab, Inc. ("Berkeley"), BlueWave Healthcare Consultants, Inc. ("BlueWave"), Floyd Calhoun Dent, III ("Dent"), Robert Bradford Johnson ("Johnson"), and Latonya Mallory ("Mallory") (collectively "Defendants").

Defendants violated the Anti-Kickback Statute ("AKS"), 42 U.C.S. §1320(a)-7b(b)(1)(A), by knowingly and willfully offering and/or paying kickbacks, primarily in the form of improper "process and handling" fees, to induce physicians to refer blood samples to "specialty laboratories" Berkeley, Health Diagnostic Laboratories, Inc. ("HDL"), and Singulex, Inc. ("Singulex") for large panels of tests, many of which were medically unnecessary. This conduct resulted in false or fraudulent claims submitted to Medicare and TRICARE which caused those programs to pay more than five hundred million dollars ($500,000,000.00) to Berkeley, HDL, and Singulex, all in violation of False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733. Defendants also violated the AKS by routinely waiving copayments and deductibles owed by TRICARE patients, and causing false claims tainted by those kickbacks to be presented to, and paid by, the TRICARE program, also in violation of the FCA.

Finally, Defendants BlueWave, Johnson, Dent, and Mallory also violated the AKS by entering into illegal contracts for commission-based payments paid to BlueWave in exchange for arranging for and recommending the referral of patients to HDL and Singulex for testing. The actions of BlueWave, Johnson, Dent and Mallory caused HDL

and Singulex to submit to Medicare and TRICARE claims for payment for the testing services tainted by this illegal kickback scheme, in violation of the FCA.

2. **Local Civil Rule 26.03(A)(2)**: The names of fact witnesses likely to be called by the party and a brief summary of their expected testimony.

Deposition discovery will likely be extensive. The United States intends to conduct discovery into all elements of each allegation alleged in the Complaint in Intervention against each Defendant. At this early stage it is not clear which witnesses the United States will ultimately call. The United States anticipates working with Relators, who may conduct discovery into allegations in which the United States declined to intervene, to coordinate and share depositions. Together with Relators, we anticipate needing approximately forty (40) depositions to prepare this case for trial, exclusive of depositions of experts and any counsel, as discussed below.

There are several categories of witnesses who will be deposed, including Defendants, current and former sales representative witnesses, current and former employees, physicians and physician witnesses, two laboratories (Health Diagnostics Laboratories, Inc. (HDL) and Singulex, Inc. (Singulex)) that have settled with the United States, and Relators for their liability for the alleged conduct and who have evidence relevant to the liability of remaining Defendants, and others with information relevant to the alleged conduct.

During the investigation, all remaining Defendants asserted that they reasonably relied upon the advice of counsel when they engaged in the alleged conduct. Any such assertion will require the United States to conduct additional discovery, including depositions.

Other than the depositions of experts and counsel, the fact witnesses likely to be called by the United States include:

(a) Party Witnesses:

- United States Witnesses – Medicare and TRICARE witnesses will present evidence regarding the programs and payment for clinical lab testing and other testimony relevant to the allegations in the Complaint in Intervention and Answers thereto;
- Defendants – Defendants are likely to be called as witnesses and are expected to testify about all allegations in the Complaint in Intervention and Answers thereto;
- Relators – Relators are likely to be called as witnesses and are expected to testify about all allegations in the Complaint in Intervention and Answers thereto.

(b) Former Sales Representative Witnesses:

The following former sales representatives are likely to be called as witnesses and are expected to testify about Defendants' sales and marketing practices; the provision of process and handling fees and other things of value to referring physicians or their staff; the routine waiver of copayments and deductibles; testing services, test panels, medical necessity and marketing of test clinical value; the process and handling work involved to prepare blood samples for shipment; the relationships between and communications amongst the Defendants, their employees, entities owned or controlled by any Defendant, physicians and physician practice employees and sales representatives; the structure of BlueWave, the relationships between BlueWave and sales representatives; sales representative compensation, training, oversight, audit and compliance with legal requirements, including the AKS and FCA and other topics on which the witnesses have information relevant to the allegations in the Complaint in Intervention and Answer thereto:

- Leonard Blasko

- Thomas Anthony Carnaggio
- Charles Maimone, Jr.
- Additional current or former sales representatives associated with Defendants, including but not limited to those listed in the roster produced to the United States June 25, 2013, with bates number BLUW000007-000010.

(c) Physicians and Physician Practice Employees**:**

The following physicians, physician practices and their employees are likely to be called as witnesses and are expected to testify about Defendants' sales and marketing practices; the provision of process and handling fees and other things of value to referring physicians or their staff; the routine waiver of copayments and deductibles; testing services, test panels, medical necessity and marketing of the tests' clinical value; the process and handling work involved to prepare blood samples for shipment; relationships and communications with the Defendants, entities owned or controlled by any Defendant and sales representatives; and other topics on which the witnesses have information relevant to the allegations in the Complaint in Intervention and Answer thereto.

- Heritage Medical Partners
- Dr. Lloyd Miller
- Dr. Bodo Brauer
- Dr. Jeffrey Gladden
- Dr. Rex Butler
- Colorado Springs Family Practice
- Dr. Lawrence A. May
- Family Physicians of Spartanburg

- Keowee Primary Care & Internal Medicine
- Additional physicians and practices

(d) Counsel:

During the United States' investigation, all Defendants asserted, to some degree or another, that they reasonably relied on the advice of counsel when engaged in the conduct giving rise to their liability. Therefore, the United States has reason to believe Defendants will assert an advice of counsel defense. The United States anticipates seeking the testimony of witnesses with evidence relevant to any advice of counsel defense, including evidence regarding the reasonableness of any supposed reliance, in addition to other discovery of evidence relevant to any purported reasonable reliance on the advice of counsel.

(e) Other**:**

- HDL is likely to be called as a witness and is expected to testify about all allegations in the Complaint in Intervention and Answers thereto
- Singulex, Inc. is likely to be called as a witness and is expected to testify about all allegations in the Complaint in Intervention and Answers thereto
- Additional individuals and entities

3. Local Civil Rule 26.03(A)(3): The names and subject matter of expert witnesses (if no witnesses have been identified, the subject matter and field of expertise should be given to experts likely to be offered).

The government intends to call experts to opine on the following subject matters:

a. An physician expert to opine as to the medical necessity of the tests and test panels marketed by Defendants and billed to the Medicare and TRICARE programs;

b. An expert in clinical testing to opine as to the medical necessity of the tests and test panels marketed by Defendants and billed to the Medicare and TRICARE programs;

c. An expert in valuation to opine on fair market value to rebut Defendants' assertion of fair market value;

d. An expert to opine on the economics of the business models used by Defendants;

e. An expert to determine the damages suffered by the United States, including the amounts paid by the United States by mistake of fact and the amounts by which Defendants were unjustly enriched.

4. **Local Civil Rule 26.03(A)(4):** A summary of the claims or defenses with statutory and/or case citations supporting the same.

The AKS prohibits the knowing and willful solicitation or receipt of remuneration to induce the purchase of a good or service for which payment may be made under a federal health program. 42 U.S.C. § 1320a-7b(b)(1)(A). A claim that includes items or services resulting from a violation of the AKS also constitutes a false claim for purposes of the FCA. 42 U.S.C. § 1320a-7b(g). Payments are not considered "remuneration" under the AKS if Defendants prove that they met every element of an enumerated safe harbor under the AKS. The safe harbor at issue here is the Personal Services and Management Contracts safe harbor. 42 C.F.R. § 1001.952(d). To fall within that safe harbor, Defendants have the burden to prove that each of seven standards have been met, including that the "aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length

transactions, and is not determined in a manner that takes into account the volume or value of any referrals . . . ." *Id.*

Berkeley, BlueWave, Dent, Johnson, and Mallory offered and facilitated the payment of process and handling fees for the purpose of inducing physicians to refer patients for testing and to order medically unnecessary tests. Moreover, BlueWave sales representatives, including Dent and Johnson, routinely increased referrals for their client labs by encouraging physicians to order tests from both HDL and Singulex for the same patient encounter so that the physician would receive increased process and handling fees. The process and handling fee arrangements at issue here do not fall within the Personal Services and Management Contracts safe harbor because at least one safe harbor element was not met.

Also, the sales agreements between BlueWave and its customer labs, HDL and Singulex, violate the AKS. As noted above, the AKS prohibits receiving remuneration in return for "arranging for or recommending purchasing . . . or ordering" any "good" or "service" reimbursed by federal health programs. 42 U.S.C. § 1320a-7b(b)(1)(B). Singulex and HDL paid BlueWave – in the form of a percentage of revenue that the labs collected – for "arranging for or recommending purchasing" tests that were reimbursed by federal health programs. Such compensation arrangements are permitted if the sales representative is the laboratory's own employee. The BlueWave sales representatives were independent contractors, not employees of the labs. Medicare and State Health Care Programs; Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952, 35981 (July 29, 1991). Multiple Advisory Opinions and OIG statements address the impropriety of such third party marketing arrangements. See, e.g., HHS-OIG Advisory Opinion No. 99-3 (Issued March 1999), *available at*

https://oig.hhs.gov/fraud/docs/advisoryopinions/1999/ao99_3.htm; HHS-OIG Advisory No. Opinion 10-23 (Issued October 2010), *available at* https://oig.hhs.gov/fraud/docs/advisoryopinions/2010/AdvOpn10_23.pdf.

5. **Local Civil Rule 26.03(A)(5):** Absent special instructions from the assigned judge, the parties shall propose dates for the following deadlines listed in Local Civil Rule 16.02: (a) Exchange of Fed. R. Civ. P. 26(a)(2) expert disclosures; and (b) Completion of discovery.

The Joint Submission summarizes the discovery deadlines sought by each party. The United States needs the additional time to conduct sufficient discovery to bear its burden of proof for its allegations. In addition to the depositions described above, the United States seeks to conduct paper discovery of Defendants and others into each element of each claim asserted against each Defendant in the Complaint in Intervention or the Answers thereto. This amount of discovery is necessary due to the large scale, disperse nature of Defendants' conduct. The special circumstances described below, in response to Local Civil Rule 26.03(A)(6), add a level of complexity and difficulty that will require time, effort and cooperation between the parties.

Proposal Regarding Staggered Expert Report Deadlines

In its Conference and Scheduling Order, entered on November 5, 2015, the Court proposed a deadline of March 3, 2016, for Plaintiffs to file and serve their experts reports, and a deadline of April 4, 2016, for Defendants to do the same. The parties have proposed alternative dates for expert discovery. As discussed above, Defendants may assert that their conduct fell within a safe harbor of the AKS and therefore bear the burden of proof for each element of any such defense. Defendants may seek to offer expert evidence regarding application of an AKS safe harbor, or any other issue on which

Defendants bear the burden of proof. If Defendants offer such expert evidence, Plaintiffs should have an opportunity to rebut with an expert of their own.

Therefore, the United States and all Relators request that the initial deadline listed in the Final Scheduling Order for identifying and disclosing expert reports also include any expert witness proposed by a Defendant on any issue for which the Defendant bears the burden of proof, if any. Further, the United States and all Relators request that the second Expert Witness deadline in the Final Scheduling Order include any expert witness proposed by the United States or a Relator to rebut an expert witnesses proposed by a Defendant on an issue for which the Defendant bears the burden of proof, if any.

6. **Local Civil Rule 26.03(A)(6):** The parties shall inform the Court whether there are any special circumstances which would affect the time frames applied in preparing the scheduling order. See generally Local Civil Rule 16.02(C) (Content of Scheduling Order).

There are special circumstances that will affect the time frame for discovery in this matter. This lawsuit raises complex issues, involves multiple parties, and may give rise to difficult legal questions. During the November 30, 2015, telephonic conference held with all the Parties, the United States informed the other parties of a number of issues that will affect the time frame for discovery in this matter.

The United States informed all the Parties that the United States has in its possession, custody or control documents and information that may be subject to discovery that were obtained by the United States from third parties in response to investigative requests for information, subpoeanas and Civil Investigatory Demands ("CID") issued pursuant to the False Claims Act, 31 U.S.C. § 3733. Most, if not all, of this information is available from other sources, such as the third party that originally produced the Information to the United States.

The United States' ability to timely produce such information and documents, and the Parties' ability to use the information and documents unencumbered are affected by certain legal obligations and limits. For example, documents and information obtained via CID are subject to the limitations of 31 U.S.C. § 3733. Certain third parties that produced documents and information asserted that they contain information protected by a privilege, trade or business secret belonging to the third party, and/or are subject to a Confidentiality Agreement and/or a Waiver Agreement, pursuant to which the documents and information was produced to the United States in the first instance.

During the Rule 26(f) Conference, the United States informed the other parties that the Medicare and TRICARE programs, and the entities that manage them, are large complex public institutions with a number of government privileges in addition to the attorney-client privilege and work product doctrines.[1]

Another circumstance that may affect the timing and volume of discovery is the anticipated assertion, regarding at least some of the fraudulent schemes, that Defendants reasonably relied on the advice of counsel when engaged in the alleged wrongful conduct. The United States is likely to seek documents and information – to include deposition testimony – relevant to any advice of counsel, including evidence regarding the reasonableness of any purported reliance. It is difficult to estimate the scope of such

[1] During the November 30, 2015, Rule 26 Conference, the United States also informed the Parties that some of the Government information that may be subject to discovery is contained in large databases or on proprietary software and that the United States will work with the Parties to obtain the information sought by the Parties. The United States also informed the Parties that Government electronic information that may be subject to discovery may exist on disaster recovery tapes, temporary or cache files and are not reasonably accessible but that any such information is likely completely duplicative of reasonably accessible information.

discovery at this stage because it is unknown which Defendants may claim reasonable reliance on counsel, or which conduct they will claim it for.

7. **Local Civil Rule 26.03(A)(7)**: The parties shall provide any additional information requested in the Pre-Scheduling Order (Local Civil Rule 16.01) or otherwise requested by the assigned judge.

The United States believes that all information requested by the Court is contained in the Joint Submission or an exhibit thereto, or this LR 26.03 report.

The United States makes this report based upon the information currently available to the United States Department of Justice, Civil Division and the United States Attorney's Office for the District of South Carolina, but notes that the investigation of this matter is continuing and may result in the discovery of additional information in the future. The United States may therefore amend this report.

Respectfully Submitted,

BENJAMIN C. MIZER
Principal Deputy Assistant Attorney General
Civil Division

WILLIAM N. NETTLES
United States Attorney

s/ James C. Leventis, Jr.
JAMES C. LEVENTIS, JR. (#9406)
JENNIFER ALDRICH (#6035)
Assistant United States Attorneys
United States Attorney's Office
1441 Main Street, Suite 500
Columbia, S.C. 29201
Telephone: (803) 929-3000
James.Leventis@usdoj.gov

MICHAEL D. GRANSTON
PATRICIA L. HANOWER
ELZABETH STRAWN
MARY CHRIS DOBBIE
MICHAEL SHAHEEN

Attorneys, Civil Division
United States Department of Justice
P.O. Box 261, Ben Franklin Station
Washington, D.C. 20044
Telephone: (202) 353-0506
Michael.E.Shaheen@usdoj.gov

December 14, 2015